

REMARKS/ARGUMENTS

Applicants' attorney and Dr. Klimyuk wish to extend their thanks to the Examiner for his courtesies in granting the personal interview conducted on September 7, 2006. In view of the issues and proposals discussed during the interview, Applicants are amending independent claims 1, 18 and 38, to recite that the "exogenous nucleic acid comprises at least one restriction site". Support for these amendments are found in claim 13, throughout the specification, i.e., pages 11-12, and Examples I-II. Thus, Applicants are simply introducing the recitation of a dependent claim into independent claims. Accordingly, claim 13 has been cancelled, and claim 12 has been amended to recite that the "at least one restriction site comprises at least one recombination site. . ". Also as explained at the interview, claims 4, 19, 43 and 44 have been cancelled to expedite prosecution and reduce the number of issues. In addition, the specification on page 7 has been amended to correct a typographical error with regard to the *Lee, et al.* citation. No new matter has been added. Entry of these amendments is respectfully requested.

35 U.S.C. §112

Claims 4, 19, 43 and 44 have been rejected under 35 U.S.C. § 112, first paragraph as lacking enablement. Claims 4, 43 and 44 have been rejected under 35 U.S.C. § 112, second paragraph as indefinite. Claims 4, 19, 43 and 44 have been cancelled rendering these rejections moot.

35 U.S.C. § 103

The Examiner has maintained the rejection of claims 1, 2, 5-9, 11-16, 18, 19, 36-41, 43 and 44 as obvious over *Famelaer et al.*, *Theor. Appl. Genet.*, 79:513-520 (1990) ("*Famelaer*"), in view of *Blume et al.*, *Plant J.*, 12:731-746

(1997) ("*Blume*"), and *Adam et al.*, *Plant J.*, 11:1349-1358 (1997) ("*Adam*"). Claims 4, 19, 43 and 44 have been cancelled making the rejection moot as it pertains to those claims.

The Office has determined that it would have been obvious to one skilled in the art to modify *Famelaer* which teaches the production of parasexual hybrid plants through fusing gamma-irradiated protoplasts with non-treated protoplasts, by using protoplasts from transgenic plants as taught by *Blume*, and YAC vectors as taught by *Adam*. (Office Action p. 6-7). Applicants respectfully traverse the rejection.

Applicants argued that the collective teachings of the publications cited by the Examiner would not have suggested or motivated one skilled in the art to produce the claimed invention with any reasonable expectation of success. Applicants specifically pointed out that the cited prior art, particularly *Famelaer*, does not teach or suggest transformation of protoplasts with the exogenous nucleic acid prior to irradiation, or selection for artificial minichromosomes containing the exogenous nucleic acid and that exhibit normal plant chromosomal activities.

The Examiner's rebuttal is that "it is not necessary that a reference actually suggest changes that Applicants made". Office Action p. 6. The Examiner's contention is that notwithstanding the lack of any suggestion in the art, one skilled in the art would have been motivated to modify *Famelaer* by using transgenic lines to introduce a desired trait of a transgene into a desired recipient line, solely on the basis of "common knowledge and common sense". Office Action p. 6. This position is not legally supportable.

An obviousness rejection cannot be based solely on the fact that the missing step is old in the art. As stated by the Federal Circuit, "Virtually all inventions are combinations and virtually all are combinations of old elements. A court must

consider what the prior art as a whole would have suggested to one skilled in the art". *Environmental Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 218 USPQ 865 (Fed. Cir. 1983) (finding that a combination of known chemical reactions did not render the invention based on those reaction obvious). See also *Rosemount, Inc. v. Beckman Instruments, Inc.*, 727 F.2d 1540, 1546, 221 USPQ 1, 7 (Fed. Cir. 1984) ("A combination may be patentable whether it be composed of elements all new, partly new, or all old".).

Moreover, the Federal Circuit has held that general conclusions concerning what is "basic knowledge" or "common sense" to one of ordinary skill in the art, without specific factual findings and some concrete evidence in the record to support those findings, will not support an obviousness rejection. *In re Zurko*, 258 F.3d 1379, 1386, 59 USPQ2d 1693, 1697 (Fed. Cir. 2001) (reversing the finding of obviousness). As stated in that case, the Board cannot simply reach conclusions based on "its assessment of what would be basic knowledge or common sense. Rather, the Board must point to some concrete evidence in the record in support of these findings". *Id.* Absent any supporting evidence or reasoning, the determination that motivation to combine exists exclusively on the basis of "common knowledge and common sense" amounts to nothing more than an attempt by the Office to shift the initial burden of establishing a *prima facie* case of obviousness on Applicants, thus requiring Applicants to disprove obviousness before it is even established.

The PTO has the burden under section 103 to establish a *prima facie* case of obviousness. . . . It can satisfy this burden only by some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references.

In re Fine, 837 F.2d 1071, 1074 (Fed. Cir. 1988) (internal citations omitted). Conclusory statements made by the Examiner regarding a claim element fail to satisfy the requirement for an "objective teaching" regarding that claim element. *In re Zurko*, 258 F.3d at 1386, 59 USPQ2d at 1697. Thus, in this case, as a matter of law, a *prima facie* case of obviousness has not been established.

In any event, *Famelaer* does not teach or suggest a reproducible method of making a plant artificial chromosome that contains exogenous nucleic acid comprising at least one restriction site, as recited in the amended claims. *Famelaer* teaches transfer of native (*i.e.*, non-exogenous) donor DNA via fusion of irradiated and non-irradiated protoplasts to create a parasexual hybrid plant containing a random number of chromosomes from a donor plant. *Famelaer*, at 513, 516-518. Although the method results in the production of some chromosome fragments, *Famelaer* found that they were not stably inheritable. *Id.* at 517. For example, he found that the ME isozyme (malic enzyme (Me, EC 1.1.1.42)) was not expressed in any of the hybrids, and the ShDh isozyme (Shikimate dehydrogenase (ShDh, EC 1.1.1.25)) was almost completely lost as early as the first generation progeny. *Id.* at 514, 517-518.

In view of the amendatory language that has now been introduced into the independent claims, the distinctions between the claimed invention and the cited prior art become even more pronounced. As disclosed in pages 8 and 10-12 of the present specification, the recombination sites allow for further genetic manipulation and movement of the artificial chromosome after its "selection". In view of *Famelaer's* observations with respect to the behavior of the chromosome fragments, a person of ordinary skill in the art would not have been motivated with any reasonable expectation of success to modify *Famelaer's* method to

produce a plant artificial chromosome by transforming protoplasts with exogenous nucleic acid comprising at least one restriction site, irradiating the protoplasts to produce chromosome fragments, fusing the protoplasts with protoplasts of a second plant species, and selecting for artificial minichromosomes containing the exogenous nucleic acid that exhibit normal plant chromosomal activities.

The secondary references, *Blum* and *Adam*, disclose methods of plant transformation. Neither of these publications cures the deficiencies of *Famelaer*.

In conclusion, the collective teachings of *Famelaer*, *Blume* or *Adam* do not render obvious the claimed methods. Reconsideration and withdrawal of the rejections are respectfully requested.

At this time, the Examiner is strongly encouraged to telephone Applicants' attorney at (908) 654-5000 in order to overcome any remaining issue that he might have.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

Dated: October 31, 2006

Respectfully submitted,

By Shawn P. Foley
Shawn P. Foley
Registration No.: 33,071
LERNER, DAVID, LITTENBERG,
KRUMHOLZ & MENTLIK, LLP
600 South Avenue West
Westfield, New Jersey 07090
(908) 654-5000
Attorney for Applicants